K040431

MAR 1 0 2004

510(k) Summary - Tina-quant IgM Gen.2

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
Submitter name, address, contact	Roche Diagnostics 9115 Hague Rd Indianapolis IN 46250 (317) 521-3831 Contact person: Sherri L. Coenen Date prepared: February 17, 2004
Device Name	Proprietary name: Roche Diagnostics Tina-quant IgM Gen.2 Common name: Tina-quant IgM Gen.2 Classification name: IgM (Mu chain specific) antigen, antiserum, control
Device description	The Tina-quant IgM Gen.2 is an immunoturbidimetric assay. Anti-IgM antibodies react with antigen in the sample to form an antigen/antibody complex which is measured turbidimetrically.
Intended use	Immunoturbidimetric assay for the quantitative in vitro determination of IgM in human serum and plasma on Roche automated clinical chemistry analyzers.
Predicate Device	We claim substantial equivalence to the currently marketed Roche Diagnostics Tina-quant IgM assay. (K955908).

Reagent Summary

The following table describes the similarities and differences between the Tina-quant IgM Gen.2 and the predicate device.

Topic	Tina-quant IgM (K955908)	Tina-quant IgM Gen.2 (Modified Device)
Intended Use	Immunoturbidimetric assay for the quantitative in vitro determination of IgM in human serum and plasma on automated clinical chemistry analyzers.	Same
Method	Immunoturbidimetric assay	Same
Sample type	Serum Plasma: Heparin, EDTA	Same
Measuring range	Roche/Hitachi 902: 30 - 490 mg/dL Roche/Hitachi 904/911/912/917/Modular: 25 - 650 mg/dL 3 - 5362 mg/dL with rerun	*Standard Application:* Roche/Hitachi 902: 25 - 650 mg/dL Roche/Hitachi 904/911/912/917/Modular: 25 - 650 mg/dL 3 - 3660 mg/dL with rerun *Sensitive Application:* Roche/Hitachi 902: 4 - 150 mg/dL Roche/Hitachi 904/911/912/917/Modular: 4 – 150 mg/dL 1 – 450 mg/dL with rerun
Expected values	40 - 230 mg/dl	Adults: 40 – 230 mg/dL Additional ranges for children 0 – 19 years

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 0 2004

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: k040431
Trade/Device Name: Roche Diagnostics Tina-quant IgM Gen.2
Regulation Number: 21 CFR § 866.5550
Regulation Name: Immunoglobulins (Light Chain Specific) Immunological Test System
Regulatory Class: II
Product Code: DAO
Dated: February 17, 2004
Received: February 19, 2004

Dear Ms. Coenen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K040431

Device Name: Tina-quant IgM Gen.2

Indications For Use:

Immunoturbidimetric assay for the quantitative in vitro determination of IgM in human serum and plasma on Roche automated clinical chemistry analyzers.

Measurement aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040431